84-2900

No. 84-____

Supreme Court, U.S.
FILED
AUG 20 1984
ALEXANDER L. STEVAS,
CLERK

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1984

ORTHO PHARMACEUTICAL CORPORATION,
*Petitioner,*

—v.—

CAROL LYNN WOODERSON,
*Respondent.*

## PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF KANSAS

DAVID F. DOBBINS
PATTERSON, BELKNAP, WEBB & TYLER
30 Rockefeller Plaza
New York, New York 10112
(212) 541-4000

*Counsel for Petitioner Ortho Pharmaceutical Corporation*

*Of Counsel:*

GEORGE S. FRAZZA
ROGER S. FINE
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(201) 524-0400

38 pp

## QUESTIONS PRESENTED

1. Does the Supremacy Clause preempt individual states from forcing makers of prescription drugs sold in interstate commerce to include warnings in the prescribing instructions found impermissible under federal law and at variance with the purposes of that federal law?

2. Does a refusal of a state court to make available to an out-of-state defendant that state's statute apportioning negligence among *all* parties to an occurrence constitute a denial of equal protection?

## LIST OF PARTIES TO THE APPEAL IN THE SUPREME COURT OF THE STATE OF KANSAS

The names of all of the parties to the appeal in the Supreme Court of the State of Kansas are provided in the caption to this petition. Sup. Ct. R. 21.1(b). Ortho Pharmaceutical Corporation is a wholly owned subsidiary of Johnson & Johnson. Pursuant to Rule 28.1, the following are all of the affiliates of Johnson & Johnson, other than wholly owned subsidiaries:

ens Biologicals, Inc.
Enzo Biochem, Inc.
Immunomedics, Inc.

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## PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF KANSAS

## OPINIONS BELOW

The opinion of the Supreme Court of Kansas dated April 27, 1984, reported at 235 Kan. 387, 681 P.2d 1038 (the "Opinion"), and its denial without opinion of the motion for rehearing by Ortho Pharmaceutical Corporation ("Ortho") on June 25, 1984, are reproduced in Appendix A. This was a direct appeal from the judgment entered by the trial court on a verdict returned in February 1983. On March 18, 1983 the trial court orally denied Ortho's motions for a directed verdict or in the alternative for a new trial (R. XL).[1]

1 Citations to " R. ____" are to the trial record; "pp. ____" refers to the trial transcript.

## JURISDICTION

The opinion affirmed a judgment of $4,750,000 in an action for damages for personal injuries by Carol Wooderson, who claimed that oral contraceptives sold by Ortho and taken by her between 1972 and 1976 caused her acute kidney failure in June 1976 (R.III, p. 382). She asserted that Ortho failed to warn her prescribing physician of a suspected risk of acute kidney failure due to hemolytic uremic syndrome ("HUS"), and that this failure to warn caused her kidney failure. Verdicts of $2,000,000 in compensatory damages and $2,750,000 in punitive damages were returned (R.III, pp. 381-2). This court has jurisdiction to review the judgment under 28 U.S.C. § 1257(3).

## CONSTITUTIONAL PROVISIONS INVOLVED

Article VI, clause 2 (Supremacy Clause):

> "This Constitution and the Laws of the United States which shall be made in pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the Supreme Law of the Land; and the Judges of every state shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

Amendment XIV:

> "No State shall. . . deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."

## STATUTES INVOLVED

§ 201(n) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 321(n); § 502(a) and (n) of the Act, 21 U.S.C. § 352(a) and (n); and § 505(a) and (d)(6) of the Act, 21 U.S.C. § 355(a) and (d)(6). These statutory provisions are set forth in Appendix B.

## SUMMARY

This petition raises simple but compelling questions of federal law that affect the very framework of federal regulation of prescription drugs. The Kansas courts in this case premised their finding of liability and the concededly "enormous" punitive damages on Ortho's failure to warn physicians of the possibility that its prescription drug Ortho-Novum might cause a specific and exceedingly rare kidney disorder. Plaintiff's position that a warning about an unproven side effect was necessary conflicts with the plenary power of the federal FDA to supervise and approve the precise wording of advice to physicians concerning prescription drugs; indeed, critical to the Kansas Supreme Court's decision to uphold the punitive damage award was its conclusion that Ortho had omitted warnings about certain possible side effects *when the FDA had already determined that such a warning should not be made.* The Kansas ruling permits and encourages each of the fifty states to develop through imposition of punitive damages in personal injury litigation an extended list of warnings that must accompany the distribution of prescription drugs within that state—even if such required warnings conflict with one another and with a contrary determination by the FDA. It was precisely to avoid such "clutter," and the attendant risk that myriad additions would defeat the purpose of the prescribing instructions, that Congress established the FDA as the arbiter not only of what prescription drug warnings should contain but what they should not contain.

This case thus raises, in an industry where federal regulation is not only extensive but is deemed to be vital to the national health, the questions left open last Term in *Silkwood v. Kerr-McGee Corp.*, ____ U.S. ____, 104 S. Ct. 615 (1984), that is, whether an "award of punitive damages" is preempted because it "conflict[s] with the federal remedial scheme. . . ." 104 S. Ct. at 617. The Court should review this case, and the important federal constitutional issues of regulatory preemption it raises, before its emulation by the other states threatens chaos in the vitally important area of prescription drugs, with attendant risks to the national health.

## STATEMENT OF THE CASE

HUS is a rare kidney disorder of unknown origin which occurs spontaneously in young women.[2] It is conceded that no one to this day knows whether oral contraceptives ("o.c.'s") in fact cause HUS. Many thousands of young women, however, ingest o.c.'s continuously over a period of years. Thus inevitably some women will have HUS or some other spontaneously occurring disorder coincidentally with their use of o.c.'s. At the time of Mrs. Wooderson's illness there had been only nineteen such cases (p. 1408). Mrs. Wooderson's was the first alleged incident of HUS in a woman taking Ortho-Novum ever reported to Ortho (p. 2243-45).

Under the common law of Kansas, as in virtually every other jurisdiction, liability for personal injuries caused by a prescription drug requires (a) proof that the seller of the prescription drug in the exercise of reasonable care should have placed in the prescribing instructions (sometimes referred to herein as the "package insert" or the "labeling" for the drug) a warning to prescribing physicians about the particular side effect, and

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2 HUS usually occurs in children (male or female) or young women (pp. 600, 935, 2356). Its symptoms are a significant drop in platelets (small disc-like particles in the blood which initiate blood clotting), insufficient kidney function (diagnosed by an abnormally high level of waste product—urea—found in the blood) and hemolytic anemia (rapid destruction of red blood cells) (pp. 597, 910).

(b) that had such a warning been given, the prescribing physician would have taken appropriate steps to avoid the injury.[3]

In this case, plaintiff never contended that liability for compensatory damages should be imposed on Ortho for failing to list HUS as an established adverse reaction, but rather for not listing it in prescribing instructions as a "suspected" adverse reaction for which "an association has neither been confirmed or refuted" (p. 1438-39). Plaintiff's expert on labeling gave the following argument for adding such a warning (p. 1440):

> "A. I think we've been through this once. I feel that as of 1976, there were nine reports with at least 19 patients, maybe as many as 23, that had been reported with one patient having a rechallenge. I think that is more than enough to list it as having occurred, and since it's such a serious effect, it's a matter of prudence when you have a potentially lethal effect of a drug, even though it's—*it's still at the suspicion stage and not confirmed with any statistical evaluation*. I think prudence demands that it be identified."[4]

In support of her claim for punitive damages, plaintiff relied in part on this same failure to warn of HUS as a possible but unconfirmed side effect. Equally, if not more important for purposes of this petition, plaintiff also relied upon the absence from Ortho's physician and patient labeling during the period 1970-74 of any discussion of the results of a British epide-

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3 *E.g., Lindquist v. Ayerst Laboratories, Inc.*, 227 Kan. 308, 607 P.2d 1339 (1980); *Stanback v. Parke, Davis & Co.*, 657 F.2d 642 (4th Cir. 1981); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (o.c.). The physician functions as a "learned intermediary," and must exercise independent judgment free of manufacturer control in order to operate effectively. *E.g., Dyer v. Best Pharmacal*, 118 Ariz. 465, 577 P.2d 1084, 1088 (1978); *Stanback v. Parke, Davis & Co., supra*; Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 Rutgers L. Rev. 947, 987 (1964).

4 Unless otherwise noted, emphasis herein has been added.

miological survey done in 1969. This survey purported to find a statistically significant association between thromboembolic diseases[5] and the estrogen content of o.c.'s (DX-AA).[6] The Opinion placed great reliance upon a "Dear Doctor" letter[7] sent by the FDA in January 1970 enclosing the uniform labeling promulgated by the FDA for *all* o.c. products (681 P.2d at 1062-63; a-104-6[8]) (PX-8F). This labeling was in effect from 1970 through 1974 (pp. 2063-65, 2129). As indicated in the Opinion (*id.*), this Dear Doctor letter was written primarily to bring the new uniform labeling for o.c.'s to the attention of prescribing physicians. However, while the letter did make reference to the British survey, the letter noted that its finding "has not been confirmed by other studies."

The major predicate in the Opinion for affirming the punitive damage award is that "Ortho played down the British report" and, further, "that Ortho continued to urge the use of its higher estrogen products" (*id.* at 1063; a-109), *i.e.*, urged the use of 1/80 as opposed to 1/50.[9] However, this British survey was limited to specific thromboembolic diseases and

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5 The thromboembolic diseases specifically discussed were thrombophlebitis, pulmonary embolism and strokes. Thrombophlebitis means inflammation and blockage of a vein by a blood clot. An embolus is a clot which has broken off and travelled downstream. A pulmonary embolus (or embolism) is a clot which has originated in a vein, travelled downstream into the right side of the heart and then pumped out into a lung bed. A stroke is usually caused by a thrombus or thromboembolus in a vessel supplying blood to the brain.

6 Most o.c.'s are combination drugs consisting of a relatively small amount of estrogen, a female hormone, and a relatively large amount of progestin, another female hormone.

7 A "Dear Doctor" letter is a mass mailing sent to all prescribing physicians.

8 Citations to "a-____" are to Appendix A.

9 The "80" and "50" refer to the amount of estrogen, in micrograms, in each pill.

had nothing whatsoever to do with acute kidney failure or HUS (pp. 2071-81; DX-AA). Moreover, it is likewise undisputed that Ortho analyzed this survey and concluded that it was methodologically flawed and statistically invalid (pp. 2096-97; pp. 2404-06).

In apparent awareness of these facts, the Kansas Supreme Court concluded that a drug manufacturer " 'may not ignore or discount that information [tending to show the existence of a certain side effect] in drafting its warning solely because it finds it to be unconvincing' [citation omitted]" (681 P.2d at 1044; a-67). This statement *omits the fact—critical to this petition—that the FDA had also found the British study to be unconvincing.*

Searle, another o.c. maker, wrote the FDA on April 30, 1970, referring to these same British findings and requesting permission to amend its labeling for o.c.'s to reflect these findings (R. L, p. 127). The FDA refused, informing Searle in writing that its "proposal has been carefully considered and found to be unacceptable" (pp. 565-87; DX-CC).

This action by the FDA *prohibiting* another drug company from amending its label to disclose the British study was critically relevant on the scope of Ortho's alleged duty to include warnings of the same study. But the trial court excluded this correspondence on the incredible ground that it was not relevant, and further found that it was not clear whether all of the underlying documents relating to this attempt at effecting a labeling change were produced (p. 2154-55). It was clear, however, that the request and rejection were produced at trial, and the trial court was made aware that the uniform labeling requirements for 1970-74 were never changed to reflect the survey. The Supreme Court of Kansas did not discuss the exclusion of this rejection by the FDA of Searle's request, and also ignored the FDA's dismissal of the 1969 survey in affirming the punitive damage award, which it conceded was "enormous" (681 P.2d at 1064; a-113).

In sum, the Kansas courts permitted a multi-million-dollar punitive damage award to be based in principal part on the

1969 British survey even though the documented evidence showed a) that the FDA regarded the 1969 British survey as unconfirmed and rejected a proposed labeling change to reflect the findings of this 1969 survey; b) Ortho's own contemporaneous analysis revealed this survey to be methodologically unsound, and c) the uniform labeling for o.c.'s, which the FDA promulgated, placed in effect in January 1970, and required to be maintained in effect during the years 1970-74, did not reflect the results of this survey. Thus, in this case Kansas has assessed punitive damages against Ortho to "punish" it under Kansas common law for failure to add a warning that the FDA had already found "unacceptable."[10]

The first federal question sought to be reviewed herein, the conflict between the FDA's policies and regulations and plaintiff's theory of Kansas law, was raised at trial, both during the testimony of Dr. Samuel A. Pasquale (pp. 2047, 2053, 2058-2062, 2163), and again when the trial court refused to consider proof that the estrogen-dose warnings plaintiff demanded were forbidden by the FDA (pp. 2140-2152). The issue was also presented in Ortho's Amended Motion for a New Trial, based on the newly discovered evidence that the FDA had in 1982 specifically disapproved warnings by Searle about HUS (R. IV, pp. 565-87). The trial court inexplicably ruled this new evidence was not relevant (R. XXXXII, p. 37). The argument was repeated on appeal to the Kansas Supreme Court (Br. of Appellant, pp. 11-21). The Court brushed off the plain proof that Ortho could not have warned about HUS without violating the FDA's directives with the incredible statement that the FDA's letter to Searle was not a "clear determination" that HUS did not merit a warning (p. 34-35). Although Ortho again pressed this federal question in its Motion for Rehearing to the Kansas Supreme Court, that motion was summarily denied (a-129).

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10 Significantly, the Kansas legislature has deferred entirely to the FDA in regard to labeling of prescription drugs marketed in the state. Kansas Food and Drug Statute, Kan. Stat. Ann. §§ 65-669(n), 65-669a (1983).

The question whether the Kansas court's refusal to apply that state's comparative negligence law deprived Ortho of due process has similarly been raised at every stage of the proceedings. *See* Ortho's Motion for Directed Verdict or New Trial (p. 15-22); Br. of Appellant, p. 27-31; Motion for Rehearing (p. 1-4). The claim was rejected at all levels.

## THE REASONS FOR GRANTING THE WRIT

### I. PUNITIVE DAMAGES ASSESSED AGAINST A DRUG COMPANY FOR COMPLYING WITH FEDERAL REGULATORY DIRECTIVES REGARDING LABELING CONTENT OF PRESCRIPTION DRUGS CONFLICTS WITH FEDERAL LAW AND STANDS AS AN OBSTACLE TO THE ACCOMPLISHMENT OF THE PURPOSES AND OBJECTIVES OF THE LABELING PROVISIONS OF THE FOOD, DRUG AND COSMETIC ACT

The decision below puts *all* marketers of prescription drugs in jeopardy of being assessed punitive damages by lay juries in products liability cases for distributing such drugs in accordance with the mandates of the FDA.

The assessment of punitive damages in products cases has become increasingly commonplace.[11] The rationale of *Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967), which recognizes the bankruptcy specter inherent in permitting assessments of punitive damages for injuries for drug-induced side effects, has been effectively discarded.[12] One

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11 *See generally* Seltzer, *Punitive Damages in Mass Tort Litigation*, 52 Fordham L. Rev. 37-42 (1983); Wheeler, *The Constitutional Case for Reforming Punitive Damages*, 69 Va. L. Rev. 269, 271 (1983); Owen, *Problems in Assessing Punitive Damages Against Manufacturers of Defective Products*, 49 U. Chi. L. Rev. 1, 54 (1982).

12 Congress has expressly recognized the risk that businesses may face the choice between bankruptcy and discontinuation of a useful product line when faced with the prospect of large, cumulative awards when it drafted the

commentator notes that "whereas 25 years ago, the punitive damage case was a rarity, today it is an anomaly when one sees a complaint which does not seek punitive damages." Levit, *Punitive Damages: Yesterday, Today and Tomorrow*, 1980 Ins.L.J. 257, 259 (emphasis in original).

So far as we are aware, until recently, there had been only two punitive damage awards in prescription drug cases.[13] The law generally applied was that articulated in *G.D. Searle & Co. v. Superior Court*, 49 Cal.App.3d 22, 122 Cal. Rptr. 218 (3d Dist. 1975), which required proof of actual knowledge of a *proven* side effect coupled with failure to warn thereof. Now the proclivity for awarding punitive damages that has come to other areas of products liability is being transposed into the prescription drug liability area. These awards are being based as in this case on a lay jury's notions of gross negligence.[14] But whatever the desirability of awarding punitive damages in other kinds of products liability cases, these policy considerations clearly are inapplicable in the area of federally-supervised labeling of prescription drugs.[15]

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Proposed Federal Products Liability Act. *See* S. Rep. No. 476, *Report of the Senate Comm. on Commerce, Science and Transportation on S. 44*, 98th Cong., 2d Sess., 8-9 (May 23, 1984). This proposed legislation (and a similar House bill, H.R. 2729), reflect extensive consideration of the threat posed to the American economy by out-of-control punitive awards. *Id.* at 13, 55-62.

13 One is *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App.2d 689, 60 Cal. Rptr. 398, 418 (1st Dist. 1967) (punitive damages of $250,000), and the other was *Ostopowitz v. Wm. S. Merrell Co.*, No. 5879-1963 N.Y.L.J., Jan. 11, 1967, at 21, col. 3 (Sup. Ct. N.Y. Co. 1967) ($100,000 in punitive damages). Both of these, like *Roginsky*, involved MER 29, a withdrawn anti-cholesterol agent.

14 *See, e.g. Johnson v. Lederle Laboratories*, No. 81-C-2470 (Sedgwick Co., Kan. Dist. Ct., June 15, 1984) ($8 million in punitive damages in case involving oral vaccine); *Batteast v. Wyeth Laboratories*, No. 77L.12460 (Cook Co., Ill., Cir. Ct. July 1984) ($13 million in punitive damages in case involving prescription drug, aminophylline.

15 *See generally Roginsky v. Richardson-Merrell, supra*; *see also* Seltzer, *Punitive Damages, supra*, at 48-55; Owen, *Problems in Assessing Punitive Damages, supra*, at 27.

Prescription drugs are by definition inherently dangerous. They are nonetheless prescribed hundreds of millions of times in any given year, ingested even more often, and, given their necessarily powerful effects, unavoidably result in literally thousands of adverse reactions on a daily basis. That is why, as a matter of federal law, they are sold only under the prescription and continuing supervision of a duly licensed expert, the physician. To implement this law, Congress has delegated to the FDA the administrative function of assuring that these experts receive meaningful information in the prescribing instructions to enable them to prescribe and supervise the drug therapy as safely as possible. 21 U.S.C. § 352(n). The FDA has developed detailed procedural and substantive regulations to supervise the content of information provided to prescribing physicians and imposes sanctions for failures to comply with these procedures.

The decision in this case severely undermines the authority of the FDA, and puts every drug manufacturer and prescribing physician at risk if he complies with the FDA's standards. By its insistence that o.c. labeling set forth every possible side effect even where the FDA has determined that such a warning was inappropriate, Kansas has precipitated a fundamental collision with federal law.

Thus, this case presents the very fact situation which this Court in *Silkwood v. Kerr-McGee Corp., supra*, implicitly recognized creates a preemption by federal regulation. In *Silkwood*, this Court delineated two areas where preemption occurs even though Congress has not expressed an intent to occupy the entire field. "[S]tate law . . . is preempted to the extent it actually conflicts with federal law, that is, when it is impossible to comply with both state and federal law"; and preemption also occurs "where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress." *Id.* at 621.[16] The regulation of label-

16 *See also Jones v. Rath Packing Co.*, 430 U.S. 519, 540 (1977) (holding of preemption inescapable where it is impossible "to comply with state law without triggering federal enforcement actions").

ing content by the Kansas courts through imposition of punitive damages even though the FDA had authorized the labeling content at issue, is preempted by the Act under both tests.

### A. The Direct Conflict Between the Kansas Punitive Damage Award and The Specific Actions Taken By the FDA in Regulating Prescription Drug Labeling

As appears more fully below, the factual situation here is one which the majority in *Silkwood* implicitly recognized as creating a direct conflict between state and federal law. The *Silkwood* majority reaffirmed the basic proposition, recognized in prior decisions of this Court, that punitive damages are regulatory, rather than compensatory in purpose:

> " '[R]egulation can be as effectively asserted through an award of damages as through some form of preventive relief.' "

104 S.Ct. at 622, quoting *San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959).[17] In *Silkwood* this Court agreed with the following analysis by the District Court in denying the motion by Kerr-McGee for judgment n.o.v.:

> "The [district] court noted that Kerr-McGee 'had a duty under part 20 of Title 10 of the Code of Federal Regulations to maintain the release of radiation '*as low as reasonably achievable*.' Compliance with this standard cannot be demonstrated merely through control of escaped plutonium within any absolute amount.' . . . Therefore, the court concluded, it is not 'inconsistent [with any congressional design] to impose punitive damages for the escape of plutonium caused by grossly negligent, reckless and willful conduct.' " *Id.* at 620.

In other words, the punitive award in *Silkwood* enforced a standard under Oklahoma law that was identical to one es-

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17 *See also Smith v. Wade*, 461 U.S. 30, 103 S. Ct. 1625, 1636 (1983) (deterrence of punished conduct is "primary purpose" of punitive damages); *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 348-50 (1974) (punitive damages are "civil fines" which serve no compensatory purpose).

tablished by the federal agency—one designed, understandably enough, to keep radiation levels "as low as reasonably achievable." The conclusion of the *Silkwood* jury that Kerr-McGee in fact violated this standard, and did so in reckless disregard of public safety, did not conflict with the standard announced by the federal regulator, the NRC. The majority in *Silkwood* therefore concluded that there was no "irreconcilable conflict between the federal and state standards" and that "the imposition of a state standard in a damages action would [not] frustrate the objectives of the federal law." *Id.* at 626.

In this case, however, the state court jury in effect regulated the content of prescription drug labeling under standards diametrically opposed to those of the FDA. The Supreme Court of Kansas approved the trial court's charge to the jury that Ortho was "presumed to know of *all* potential dangers of a drug which *could* have been discovered" and had the obligation to warn of any such danger which "is serious" (R. II, p. 300). It further told the jury that while compliance with the applicable FDA regulations may be considered as evidence of due care, such compliance "does not relieve a manufacturer of the duty set forth in these [jury] instructions." The jury was further told that if Ortho was "wanton" in violating this duty created *under Kansas law* they should award as punitive damages such sum as "will serve to punish defendant, Ortho Pharmaceutical Corporation, and to deter others from like conduct." A wanton act was defined as one done with "a realization of the imminence of danger and a reckless disregard or complete indifference to the probable consequences of the act" (R. II, p. 312).

The foregoing instructions virtually compelled an award of punitive damages under the facts of this case—as they would in many instances of distribution of prescription drugs with federally approved warnings. It was not disputed that HUS is "serious" or that Ortho knew of occasional anecdotal reports of HUS among users of other types of o.c.'s prior to Mrs. Wooderson's kidney failure and that after investigation of her kidney failure, Ortho decided not to add a warning to its physician labeling that HUS was an unconfirmed but possible rare adverse reaction. Nor did Ortho contest that it did not

alter its patient warnings—which had been mandated and approved by the FDA—by adding such a warning. Thus, the jury could have concluded *under the instructions* that Ortho deliberately violated a duty under Kansas law to warn both Mrs. Wooderson's doctors and the patient herself of all potential or possible serious side effects of the drug, including HUS and acute kidney failure.

The Supreme Court of Kansas affirmed the award of punitive damages on the ground that Ortho "is under a duty [under Kansas law] to make known to the medical profession, or at least those physicians who are prescribing that drug, any of the dangerous side effects of which it knows *or has reason to know*" (emphasis in original) (681 P.2d at 1062; a-101-2), and concluded that punitive damages were properly awarded in an amount of $2.75 million because in its view the jury "could have found" that Ortho in issuing its labeling without these warnings "was grossly negligent and recklessly indifferent to the rights of others, including this plaintiff" (681 P.2d at 1064; a-112).

Punishing Ortho for violating these state-imposed duties to warn directly conflicts with federal law in a number of ways. First of all, the requirement that Ortho *must* include warnings of all suspected, but unconfirmed, serious side effects in its labeling flies in the face of FDA regulations.

Turning to the physician labeling, the FDA does not, contrary to the trial court's charge and the implicit assumption of the Supreme Court of Kansas, merely set *minimum* standards for the content of the labeling, onto which the drug manufacturer may add more warnings or other refinements as it sees fit. Section 502(a) of the Act provides that "a drug . . . shall be deemed to be misbranded (a) if its labeling is false or misleading in *any* particular." 21 U.S.C. § 352(a). With respect to prescription drug labeling, the Act directs the Commissioner to issue regulations which provide "information in brief summary relating to side effects, contraindications and effectiveness" of the drug. 21 U.S.C. § 352(n). In a 1972 preamble statement, the Commissioner of the FDA offered this formal interpretation of the Act:

> "In approving the labeling the Food and Drug Administration must determine both that the content is entirely truthful, and that it omits *no* information pertinent to the safe and effective prescribing of the drug by the physician. Congress intended the labeling to be a full, complete, honest, and accurate appraisal of the important facts that have *reliably* been proved about the drug."[18]

As part of its duty to see that the labeling "omits no information pertinent to the safe and effective use of the drug by the physician", the FDA not only regulates what is contained in the package insert, but more importantly what is *not* to be in the package insert. It determined to do so following an injunction obtained by an independent group of physicians prohibiting the FDA from requiring a warning in the labeling for certain antidiabetic drugs against alleged but unproven cardiovascular adverse reactions. *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973). The proposed labeling was rejected by the FDA for failure to comply with a regulation which at that time required the disclosure of the "existence of a difference of opinion" as to an alleged adverse reaction "if there is a material weight of opinion" to the contrary.

Following this decision, the FDA revised its basic labeling regulation to provide in pertinent part (21 C.F.R. § 1.21):

> "(a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are. . . material. . . .
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> * * * *

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18 37 Fed.Reg. 16503, 16504 (1972). These preambles are advisory opinions of the FDA, intended to let manufacturers know in advance whether their labeling will be violative of the Act, or is likely to meet with FDA approval. 21 C.F.R. § 10.85(d)(1). As such they are interpretations "of a statute by those charged with their execution" which "should be followed unless there are compelling indications that [they are] wrong, especially when Congress has refused to alter the administrative construction." *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 381 (1969); *Stevens v. Commissioner*, 452 F.2d 741, 746 (9th Cir. 1971).

(c) Paragraph (a) of this section does *not*:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act."

The FDA explained the purpose of this revision as follows:

"It is . . . apparent that there are very few statements in prescription drug labeling on which some controversy could not be found within the medical profession. Not infrequently, there are several points of view on a single issue. To permit or require statements of conflicting opinion on all of these matters would destroy the present usefulness of prescription drug labeling." 39 Fed. Reg. 33229, 33232 (1974).

The Commissioner went on to state that:

". . . if the Congress were to provide that a representation, about the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view but not misleading if the jury agreed with the experts holding the other view, it is apparent that the manufacturer would be unable to tell in advance whether his labeling violated the statute [and that it would be] undesirable to permit misleading claims to be made simply because a few experts can be found on the occasion of a trial to support them". *Id.* at 33230.

The Commissioner concluded:

"The presence of unsubstantiated medical opinion in drug labeling would be misleading within the meaning of sections 502(a) and 201(n) of the act." *Id.* at 33232.

In a further contemporaneous explanation for this change, Dr. Temple, special assistant to the Director of the Bureau of

Drugs of the FDA, in *Legal Implications of the Package Insert*, 58 Med. Clin. No. Amer. 1151, 1155 (1974), stated:

> "It is important to recognize what the package insert is and also to recognize what it is not. The most important feature of the package insert, the one that distinguishes it from other sources of information and makes possible its use as an *authoritative* reference source, is that its content must be based on substantial evidence. The labeling cannot simultaneously meet this requirement and be fully up to date. It cannot be both *authoritative* and *avant-garde*."

The Commissioner has made the same point repeatedly. For example he stated that the "statutory scheme for drug labeling is intended to provide physicians, in straightforward and concise terms, with the information they need to prescribe a drug under conditions that maximize the drug's effectiveness and minimize its risks." 44 Fed. Reg. 37434, 37436, ¶ 8 (1979).

Elsewhere he has stated:

> "Physicians clearly have access to new information on drugs through the medical literature, scientific meetings, postgraduate courses, and professional contacts with colleagues. The package insert is not intended under the law to serve as a totally current repository of all such information. It is intended instead to be an *authoritative* document which contains only those indications and usages based upon *substantial* evidence of safety and effectiveness." 40 Fed. Reg. 15392, 15394 (1975).

**1. The Conflict Over Inclusion of an HUS Warning in the 1976 Labeling**

These regulations and constructions demonstrate that the FDA's standards for approving labeling regulate what the labeling should *not* contain as well as what it should contain. In the discharge of this duty to regulate what should *not* be contained in the package insert, the FDA has decided that package inserts for o.c.'s should not be loaded up with warnings about speculative side effects, such as the HUS warning. This is precisely what it determined in rejecting the changes

proposed by Searle, discussed above. These changes, including the HUS addition, were obviously designed for products liability litigation to minimize or preclude exactly the kind of liability visited upon Ortho in this case; yet they were rejected by the FDA.

Stated another way, under the FDA's view of its role in regulating content of labeling, the issue is not whether this suspected but unconfirmed possible side effect "merits a warning", but rather whether it undermines the objectives of the Act to include such a warning. Under the established law and regulations requiring the FDA to exclude unnecessary information from the labeling, this explicit determination by the FDA—more than six years after Mrs. Wooderson's injury—that an HUS warning should not be included, coupled with its approval of the 1976 labeling without an HUS warning with full knowledge of the anecdotal reports of HUS coincident with o.c. use (pp. 2349-52), precludes Kansas from punishing Ortho for not loading up its labeling with information about this unconfirmed, possible side effect.

**2. The Conflict Over Inclusion in the Uniform Labeling of An Alleged Estrogen Dose Relationship to Thromboembolic Disease**

Kansas also punished Ortho for compliance with the uniform labeling promulgated by the FDA in omitting a reference to the findings of the British study during 1970-1974. In doing so, it created an even sharper conflict between Kansas' common law regulation and that of the FDA. In promulgating this uniform labeling, the FDA determined that it was in the best interest of the public health and welfare to require all o.c. makers to use this labeling and by telegram in January 1970 advised o.c. marketers "that use of labeling containing uniform portion other than *exactly* that in our letter of November 14, 1969, may be basis for regulatory action."

As the FDA pointed out in its "Dear Doctor" letter of January 1970 enclosing this uniform labeling, the labeling was drafted by the Obstetrics and Gynecology Advisory Committee to the FDA (PX-8F), one of several advisory committees which advise the FDA on labeling content for various classes of

drugs.[19] As noted, in promulgating this labeling drafted by the Obstetrics and Gynecology Advisory Committee, the FDA also explicitly referred to the British survey on the alleged estrogen dose relationship to thromboembolic disease in its January 1970 Dear Doctor letter enclosing the labeling. Yet it determined *not* to include the results of that study in such labeling, and forbade Searle to change its labeling to reflect this survey.

### 3. The Conflict Over the Content of Patient Labeling

The trial court in effect charged the jury that Ortho also had a duty to warn Mrs. Wooderson directly of potential serious side effects. Although the trial court recognized the established law that a drug company had no common law duty to issue warnings to the patient, he nevertheless charged the jury as follows:

> "If the manufacturer *chooses* to communicate directly with the consumer, it has a duty not to mislead the consumer so as to unduly minimize or nullify warnings which have been given to the physician or consumer" (R. II, p. 303).

The Supreme Court of Kansas sought to neutralize the patent error in creating a duty for the drug manufacturer to warn the patient directly by stating (681 P.2d at 1057; a-77):

> "We do not need to determine, in this case, what duty, if any, such a manufacturer [of prescription drugs] has to warn the ultimate consumer, the patient. Here, neither

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19 To assure that the FDA's required labeling is as unbiased and effective as possible, the agency appoints a committee of qualified experts to recommend the labeling for each of nineteen classes of drugs, e.g. anti-hypertensive, anti-inflammatory. "The committees are composed of members of the scientific and medical communities who are engaged in research and clinical practice. . . . A committee may be asked to resolve a question arising at any stage of the review process, but its activities primarily revolve around the review of NDAs and clinical guidelines." Dorsen, "Final Report of the Review Panel on New Drug Regulation" (1977), reprinted in *The Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 Before The Subcommittee on Health and Environment of the Committee on Interstate and Foreign Commerce*, 95th Cong., 2d Sess. at 599 (1978).

> was warned by Ortho, but Ortho's failure to warn the physician [of HUS] is sufficient to sustain the finding of negligence or breach of duty against it in this case."

This reasoning ignores the urging by Mrs. Wooderson's attorney of this breach of this non-existent duty as a basis for imposing punitive damages on his summation (pp. 2956, 3082).[20] There is no assurance that the punitive award was not based in whole or in part on the erroneous argument that Ortho breached some duty to warn the patient. *United New York and New Jersey Sandy Hook Pilot Ass'n v. Halecki*, 358 U.S. 613, 619 (1959), *Bose Corp. v. Consumers Union*, ____ U.S. ____, 104 S.Ct. 1949, 1969 n.2 (1984) (dissenting opinion). This final regulatory violation for which Ortho may well have been punished by the jury—namely, allegedly inadequate warnings to the patient—also sharply conflicts with federal law.

In June 1970, the FDA mandated that a brief warning be placed on the flap of o.c. drug dispensers warning users that "the most serious known side effect of oral contraceptives is abnormal blood clotting which can be fatal", and alerting them to the existence of a patient booklet. 35 Fed. Reg. 9001 (1970). The FDA further required that this patient booklet contain twelve, and *only* twelve pieces of information, and that it be made available to every patient through the prescribing physician. *Id.* at 9003.[21] Since the FDA did not permit o.c.

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20 This reasoning also ignores the testimony of Mrs. Wooderson that although she had been warned that o.c.'s exposed her to death through abnormal blood clotting, e.g., heart attacks and strokes, she was misled because there was no reference given to her regarding kidney failure and that she would not have taken the drug if she knew it might cause kidney failure (pp. 1216, 1276).

21 Thus, contrary to the trial court's charge, Ortho did not "choose" to communicate directly with the patient. Rather, in compliance with FDA regulations Ortho duly attached to the monthly drug container and included in the patient booklet the warning containing the specific language mandated by the FDA. The sole statement in the brochure not explicitly required by the terms of the FDA regulations, is this foreword (DX-B):

> "The inclusion of the following information regarding the effectiveness and known hazards of oral contraceptives is required by the Food and Drug Administration."

manufacturers to discuss the British study in the labeling directed to physicians, it necessarily would not have allowed a discussion of the arcane question of a possible relationship of estrogen dose to thromboembolic problems to be included in these simplified warnings designed for lay persons.

## B. THE REGULATION BY KANSAS OF PRESCRIPTION DRUG LABELING AS ADMINISTERED IN THIS CASE STANDS AS AN OBSTACLE TO THE ACCOMPLISHMENT OF THE PURPOSES AND OBJECTIVES OF CONGRESS

The Kansas court here indulged in a presumption that had a more detailed warning been given to Mrs. Wooderson's prescribing doctors, such a warning would have been heeded and have prevented the injury.[22] This petition does not seek a review of the use of this presumption to *compensate* victims of injuries that are found to be drug related. Use of this fiction—that warnings more elaborate than those approved by the FDA would have avoided the injury—to impose *punitive* damages, however, threatens the very purpose of the FDA regulatory function over labeling, and should be reviewed.

What the Kansas courts did in this case by imposing enormous punitive damages was to require Ortho to load up the package insert with additional warnings about specific disorders which are at times coincidental with the use of the drug. The FDA, however, has determined that such informational clutter is actually destructive of the important function of the package insert. The FDA has categorically rejected the argument "that undesirable effects 'coincidental' with the use of the drug should be included in the definition [of an adverse reaction] to protect manufacturers from product liability actions." 44 Fed. Reg. 37434 (1979). In this 1979 analysis, the FDA reiterated its philosophy in rejecting the approach to labeling used by the First Circuit in *Bradley v. Weinberger, supra*:

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22 Primarily because a more detailed warning would in virtually all cases have made no difference to the prescribing doctor, this presumption is sometimes used in drug cases as a basis for imposing liability. *See, e.g., Sterling Drug v. Yarrow*, 408 F.2d 978 (8th Cir. 1969).

> "One comment suggested that disclosure of significant medical and scientific controversy surrounding a reported adverse reaction be permitted. The Commissioner advises that inclusion in drug labeling of medical or scientific controversy concerning labeling statements would be highly confusing, and thus misleading, in violation of section 502(a) of the act." 44 Fed. Reg. at 37452.

Consequently, federal law requires that labeling be "based on data derived from human experience," 21 C.F.R. § 201.56(c), and that it advise of "known hazards and not theoretical possibilities." 21 C.F.R. § 201.57(d). *See also* 21 C.F.R. § 201.56(a) (labeling must be based on "scientific information"). The FDA has noted:

> "Labeling is not intended to be a dispositive treatise of all possible data and information about a drug. It is intended instead to advise about potential hazards and to convey documented statements concerning safety and effectiveness. The act permits labeling statements with respect to safety only if they are supported by scientific evidence.
>
> "The Commissioner concludes that drug labeling should include a contraindication only when reasonable evidence exists indicating an association between the drug and a hazard. *The Commissioner believes that including theoretical hazards as contraindications in drug labeling would cause that very important section of the labeling to lose its significance.*" 44 Fed. Reg. 37434 at 37441, 37446-47.

As stated by the Supreme Court of California in the recently decided prescription drug case *Finn v. G.D. Searle & Co.*, 35 Cal.3d 691, 200 Cal. Rptr. 870, 876, 677 P.2d 1147 (1984):

> " 'If we overuse warnings, we invite mass consumer disregard and ultimate contempt for the warning process.' (Twerski et al., supra, 61 Cornell L. Rev. at p. 521.) Moreover, both common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirma-

> tive duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given. (See Twerski, *From Risk-Utility to Consumer Expectations: Enhancing the Role of Judicial Screening in Product Liability Litigation*, 11 Hofstra L.Rev. (Spring 1983) 861, 932-935; *Thompson v. County of Alameda* (1980) 27 Cal.3d 741, 755)."

Congress has delegated the ultimate authority over labeling to the Secretary of Health and Human Services. 21 U.S.C. §§ 352, 355, 371(a). This authority has been redelegated by the Secretary to the FDA, 21 C.F.R. § 5.10(a)(1), and the FDA has proceeded to exercise that authority, 21 C.F.R § 314. Indeed, 21 C.F.R. § 10.25(b) provides that a court should in the first instance defer to the FDA's expertise. It gives the FDA "primary jurisdiction to make the initial determination on issues within its statutory mandate. . . ." This Court, in recognizing this primary jurisdiction of the FDA, stated in *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 654 (1973):

> " 'Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background.'. . . Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand."

The precise issue raised here is whether Kansas should be allowed to overrule the FDA's determination that dissertations about possible side effects that may be encountered during drug therapy and diagnosis thereof are not appropriate subjects for labeling. Kansas in effect has arrogated to itself this primary jurisdiction, and has determined to impose its views about what labeling for prescription drugs sold in interstate commerce should contain. Its direction that the labeling must contain such clutter—at risk of concededly "enormous" punitive damages—is at direct odds with the purpose of the FDA, stated time and time again, to have simple, precise and authoritative prescribing instructions.

The FDA has also rejected the argument, used by plaintiff here and adopted by the Kansas court, that the package insert should have instructed the prescribing physician how to detect and diagnosis HUS or other types of acute kidney failure:

> "Labeling is not intended to be a dispositive treatise of all possible data and information about a drug. . . . Labeling. . . cannot be transformed into the primary source of such information if it is to continue to be as concise and clear as possible." 44 Fed. Reg. 37434, 37441.

The FDA explained:

> "It [labeling] is intended instead to advise about potential hazards and to convey *documented* statements concerning safety and effectiveness." *Id.*

Overloading the package insert with all sorts of warnings of marginal or debatable relevance would truly destroy the usefulness of the package insert.

The 1984 Physicians Desk Reference Manual (the "PDR"), which contains verbatim the text of FDA-authorized warnings on most drugs, is already over 3,000 pages in length. Kansas' regulation would require that the prescribing instructions for each of the hundreds of drugs contain extended information about all serious disorders coincident with the use of the drug and that they also contain medical educational material on how to diagnose and treat such effects. This would literally require a PDR of tens of thousands of pages. The prescribing instructions included in the PDR are communications intended to convey *authoritative* information to busy professionals and as such they must, if they are to perform their function, presuppose the expertise required of a trained and licensed physician. Plainly put, prescribing instructions cannot act as surrogates for teaching someone how to practice medicine; Kansas' attempt to force FDA-mandated instructions to perform that role conflicts with the FDA's exercise of its own powers.

The actions by Kansas in assuming this regulatory role over drug labeling are analogous to that of the State of Minnesota in requiring labeling on aerosol containers in addition to that required by the FDA, which was struck down in *Cosmetic,*

*Toiletry & Fragrance Ass'n v. Minnesota*, 440 F. Supp. 1216 (D. Minn. 1977), *aff'd on opinion below*, 575 F.2d 1256 (8th Cir. 1978). The court rejected Minnesota's argument that this additional labeling was not "an obstacle to the accomplishment and execution of the full purpose and objective of Congress". *Id.* at 1224. It noted that preemption problems under the Act do not normally arise until the FDA has acted "with respect to a *specific* regulatory goal" and concluded that the FDA in this instance did so, stating:

> "[W]hen federal agencies have perceived a specific risk and have required labeling to alleviate that risk, the court feels that a state's freedom to require other than identical labeling with respect to that risk is precluded." *Id.* at 1223.

The court's reasoning as to why the action by the State of Minnesota frustrated the labeling role of the FDA is particularly pertinent here:

> "[W]here goods are distributed on a national level, a subordinate unit of the government should not be able to require that an interstate producer create special packaging or manufacture a special product for a limited distribution area *once* the federal government has acted with regard to the interest sought to be furthered by the subordinate entity's action." *Id.* at 1223-24.

The proper labeling of prescription drugs is a matter of far more serious concern than labeling for aerosol containers. Yet, unless this Court reaffirms the primacy of the FDA's determination of what is misleading or inadequate labeling, manufacturers who distribute in states which do not follow the FDA standards continue to face the risk of astronomic punitive awards. Thus, a national manufacturer could not have complied with both the mandates of the FDA and the courts of Kansas in its labeling at the same time.

Moreover, the decision of the Kansas court invites other states to force manufacturers to make similar warnings every time the facts developed in a litigated personal injury case suggest to a lay jury the advisability of such a warning—even

when the warning has been found unnecessary or even unlawful by the FDA or another state. It was precisely to avoid such conflicts that the Supremacy Clause exists and the doctrine of pre-emption has developed. The rejection of their precepts by the Kansas Supreme Court should be reviewed.

## II. STRIPPING ORTHO OF ITS STATUTORY RIGHT TO OBTAIN ADJUDICATION OF THE COMPARATIVE FAULT OF THE PLAINTIFF AND THE PHYSICIANS ON THE GROUNDS THAT THERE WAS NO EVIDENCE OF CAUSAL NEGLIGENCE DEPRIVES ORTHO OF EQUAL PROTECTION AND DUE PROCESS OF LAW

Fundamental to the Anglo-American adversary system is the right to be heard and present evidence on an issue of fact. As Chief Justice Schroeder pointed out in his dissent in the Kansas Supreme Court (681 P.2d at 1065-66; a-121-26), Ortho supposedly had the right under Kansas law, Kan. Stat. Ann. § 60-258a, to obtain an adjudication "of proportionate fault of *all* parties to the occurrence." *Brown v. Keill*, 224 Kan. 195, 580 P.2d 867 (1978). Though it is not clear from the Opinion, the Kansas Supreme Court seems to have affirmed the trial court's apparent finding that Ortho waived its right to put in its own evidence of negligence of the physicians, and that thus there was no issue of their comparative fault to submit to the jury (681 P.2d at 1059-60; a-86-94). It also ruled that there was no evidence tending to show negligence on the part of the plaintiff (*id.* at 1060; a-95). Both of these rulings are transparent pretexts for denying Ortho its right of apportionment and cannot be squared with the equal protection and due process clauses.

Turning first to the plaintiff's comparative fault, the Court ruled (*id.*):

> "There is no testimony, medical or otherwise, which suggests that this failure to go to the hospital on June 25 caused or contributed to her injuries or that her condition was reversible on June 25."

This is not accurate. Plaintiff's case on failure to warn was predicated on the undisputed fact that successful treatment of any acute kidney failure, including HUS, depends upon its being treated almost immediately after it develops. Her experts so testified (pp. 948-49; R. LXXIII, p. 180), and the Kansas Supreme Court actually faulted Ortho because it "had not alerted them [the physicians]" of the need for immediate diagnosis and treatment (681 P.2d at 1060; a-93). Had the plaintiff gone to the hospital as directed she would have been worked up and her uremia (high urea blood levels) been detected. To quote Justice Schroeder, "to declare [on this record] as a matter of law that there was no evidence . . . on the issue of plaintiff's contributory negligence is presumptuous and speculative" (681 P.2d at 1066; a-126).

What is accurate is that the trial court did affirmatively prevent Ortho from questioning its own experts as well as those of the plaintiff and plaintiff herself on the comparative fault inherent in this three-day delay in seeking treatment (pp. 494-97, 1205).

Depriving Ortho of its statutory right to apportionment because the trial court precluded it from arguing plaintiff's comparative fault is like fashioning a rule of law which presumes a person to be guilty unless he argues that he did not commit the crime and then affirming his conviction after the trial court has prevented him from making the argument. It requires no citation of authorities other than the Constitution itself to demonstrate the unfairness inherent in such a result. The Kansas court never addresses the trial court's explicit rulings precluding Ortho from arguing plaintiff's fault. Such a discussion cannot be undertaken without exposing the unconstitutional unfairness of this result.

Turning to the issue of the physicians' comparative fault in not making a prompt diagnosis, the Kansas Court seems to find a waiver by Ortho of this issue in a pre-trial conference, but it never comes to grips with Ortho's explicit reservation in the order entered in that conference of its right to put on evidence designated by the plaintiff showing the negligence of the prescribing and treating doctors. (R. I, p.7). Plaintiff

designated the deposition of her expert and his report as exhibits. Those exhibits in and of themselves contain a plethora of evidence tending to show the negligence of the doctors (R. II, pp. 179-80; R. LXXII, pp. 141-43). Thus, the Court's affirmance on the ground that "[t]here was *no* evidence, expert or otherwise, of actual, causal negligence on the part of [the treating doctors]" (681 P.2d at 1060; a-94) is subject to the same constitutional infirmity as its ruling with respect to the lack of such evidence on the part of the plaintiff herself.

The Opinion also implies that in any event there was no legitimate issue of fact with respect to the doctors' negligence. Again, the undisputed facts testified to by plaintiff's own experts are (1) that successful treatment of any acute kidney failure, regardless of cause, depends upon diagnosis and treatment as soon as possible (pp. 948-49; R. LXXIII, p. 180); (2) that Mrs. Wooderson presented with the classic symptoms of acute kidney failure; and (3) that her physicians did not make a prompt diagnosis on their own. Thus, the Court's conclusion that "plaintiff offered no evidence of causal negligence on the part of the physicians" (681 P.2d at 1060; a-94) is inaccurate. The plaintiff may not have offered the evidence for that purpose but the evidence was clearly in the record, as the dissent recognized (681 P.2d at 1065-66; a-118-19, a-125). Ortho had the constitutional right to argue this point to the jury, and the trial court precluded it from doing so (pp. 1200-07):

> "You may not by inference or otherwise attempt to draw any conclusions by the witness' answers or by your questions that the doctors are guilty of malpractice or that they were ever in this lawsuit."

## CONCLUSION

For the reasons set forth above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

DAVID F. DOBBINS
PATTERSON, BELKNAP, WEBB & TYLER
30 Rockefeller Plaza
New York, New York 10112
(212) 541-4000

*Counsel for Petitioner*
*Ortho Pharmaceutical Corporation*

Dated: August 20, 1984

*Of Counsel*:

GEORGE S. FRAZZA
ROGER S. FINE